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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/357,423	07/20/1999	THOMAS M. BAER	17726-726	9233

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/07/2001

9

Please find below and/or attached an Office communication concerning this application or proceeding.

MF-9

Office Action Summary

Application No.

09/357,423

Applicant(s)

BAER, THOMAS M.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 5-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 25-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Applicants' amendment filed on September 25, 2001 and entered as Paper No. 8. Claims 1-37 are pending. Claims 5-24 are withdrawn from consideration as being directed to non-elected subject matter. Claims 25-37 were newly added by the amendment.

Withdrawal of Rejections from Previous Office Action

The rejection of claims 1-4 under 35 USC 112, second paragraph is withdrawn in view of Applicants' amendment to the claims to further clarify the claimed invention.

The rejection of claims 1-4 under 35 USC 102 over Plakas et al is withdrawn in view of Applicants' argument that Plakas fails to teach a reagent chamber coupled with a sample carrier to form a fluidic circuit.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,741,710 to Ek.

Ek teaches a reaction vessel for processing sample and quantitatively assaying

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components in the sample. The reaction vessel contains a reaction chamber (11) having a port (12) at one end. The port is in fluidic contact with a sample carrier tube (25). See figure 1 and col. 2, line 60 – col. 3, line 17. At col. 4, lines 51-55, Ek teaches that the reaction chamber may also operate in extraction of components in the sample.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b), in view of the teachings of Ek '710.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 4, 26, 28, 29 and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,084,660 to Shartle (hereinafter Shartle '660).

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Shartle '660 discloses a device for measuring an analyte concentration of a blood sample. The device has a sample port (12), a channel (16), a measurement area (18), and a stop junction (22) (col. 5, lines 3-11). The sample port serves as a sample carrier and sample application area for introducing sample into the device. Channel (16) has a first end and a second end. The first end connects to the sample port. The second end connects to the measurement area (18). The channel provides a fluidic path between the sample port and measurement area. The measurement area provides a location for reagents to react with the sample and undergo changes providing an optical parameter for measuring the amount of analyte in the sample. The stop junction (22) provides a means for stopping flow of sample into the measurement area after it is filled. The device may be in the form of a laminate layered to form each of the chambers as shown in figure 2. In figures 7 and 8, Shartle '660 shows several different chambers having ports and conduits connected to each chamber and providing a fluid flow between the chambers.

Sample port 12 connected to layer 26, which provided a surface to which sample is applied

Shartle '660 differs from the instant invention in that 1) the reference does not specifically disclose a reaction chamber and 2) there is no specific disclosure of a pump.

With respect to the reaction chamber, as recited in claims 1 and 4, Shartle '660 discloses that the measurement area contains a reagent (20) and that the sample undergoes a change when in contact with the reagent in the measurement area (col. 5, lines 14-21 and col. 6, lines 10-12). Therefore, it would have been obvious to one of

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ordinary skill in the art that the measurement area would serve as the reaction area also.

With respect to the pump as a part of the device, Shartle '660 discloses a bladder member (14). The bladder is compressed and creates a suction force to draw the sample into the device. It is the position of the Examiner that the bladder in Shartle '660 serves as a pump mechanism, absent evidence to the contrary.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the disclosure of Shartle '660.

6. Claims 3, 25, 27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shartle '660 as applied to claims 1, 4, 26, 28, 29 and 31-37 above, and further in view of US Patent 5,627,041 to Shartle (hereinafter Shartle '041).

Shartle '660 fails to disclose a dilution chamber in the device. Shartle '660 also fails to disclose the sample processing device as a centrifuge tube.

Shartle '041 discloses a laminated sample analyzing device similar to the device described in Shartle '660. The sample analyzing device contained several layers of material formed into chambers, reservoirs and channels. The device has a sample chamber, mixing chamber, reagent chamber, and dilution chamber. Shartle '041 teaches that the dilution chamber is necessary to dilute biological sample in order to accurately detect the amount of target analyte in a sample (col. 2, lines 11-20).

Therefore, it would have been obvious to one of ordinary skill in the art to incorporate a

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dilution chamber into the device of Shartle '660 to allow more accurate measurement of the analyte content in the sample.

Regarding the processing device being a centrifuge tube, Shartle '041 discloses incorporating the laminated analytical instrument into a centrifuge cartridge to allow fixed volume assays to move fluids throughout the device. It would have been obvious to one of ordinary skill in the art to incorporate the laminate structure of Shartle '660 into a centrifuge device to help move the sample around the device and allow the sample to contact the reagents and provide the user with a quantitative measurement of the concentration of analyte in the sample.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Shartle '660 and Shartle '041.

Response to Arguments

7. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC

November 27, 2001


Jill Warden
Supervisory Patent Examiner
Technology Center 1700